

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

UNITED STATES OF AMERICA)
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)
)
v.)
)
JOSEPH MARSALA)
)
and)
)
BRENT BUMGARNER)

DOCKET NO. 3: 14cr209

BILL OF INFORMATION

Violations:

21 U.S.C. § 331(a) and 333(a)(2)

FILED
CHARLOTTE, NC

OCT 28 2014

U.S. DISTRICT COURT
WESTERN DISTRICT OF NC

THE UNITED STATES ATTORNEY CHARGES:

1. From in or about 2010 to in or about January 2014, JOSEPH MARSALA and BRENT BUMGARNER introduced into interstate commerce approximately \$800,000 in misbranded drugs with the intent to defraud the Food and Drug Administration (FDA) by falsely claiming that their drugs and products were intended for research purposes only and were not for human consumption when, in reality, MARSALA and BUMGARNER marketed the drugs and products exclusively to individuals, primarily bodybuilders, for human use.

Individuals and Entities

2. MARSALA and BUMGARNER, both residents of Charlotte, North Carolina, owned and operated Osta-Gain from in or about 2010 to in or about April 2013. MARSALA and BUMGARNER ran Osta-Gain from MARSALA's residence in Charlotte, North Carolina.

3. Through Osta-Gain and its website, www.osta-gain.com, MARSALA and BUMGARNER sold compounds containing the active ingredients in prescription drugs, amino acids/peptides, drugs, reagent chemicals, laboratory and research supplies.

4. MARSALA and BUMGARNER owned and operated Spectrum Peptides from 2013 to January 2014. Spectrum Peptides was also located at MARSALA's residence in Charlotte, North Carolina.

5. Through Spectrum Peptides and its website, www.spectrumpeptide.com, MARSALA and BUMGARNER sold compounds containing the active ingredients in prescription drugs, amino acids/peptides, drugs, reagent chemicals, laboratory and research supplies.

The Food Drug and Cosmetic Act

6. The FDA is the agency of the United States charged with the responsibility of protecting the health and safety of the American public by assuring, among other things, that drugs sold for administration to humans are safe and effective for their intended uses and bear labeling containing complete, true, and accurate information. The FDA's responsibilities include regulating the labels, labeling, distribution, and manufacture of drugs shipped or received in interstate commerce. The FDA's responsibilities also include inspecting facilities where drug products are manufactured, labeled, and packaged; examining the records at such facilities to determine whether the drugs are manufactured, labeled, and packaged under conditions whereby their quality can be assured; examining the facilities and controls used; and, where appropriate, preventing products that are improperly manufactured, labeled, and packaged from reaching the marketplace.

7. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the term "drug" includes any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or an article (other than food) intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. §§ 321(g)(1)(B) and (C).

8. Under the FDCA, a prescription drug is a drug which FDA required to be administered under the professional supervision of a practitioner licensed by law to administer such drug as a condition of FDA approving the drug to be placed on the market.

9. The FDCA prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 331(a). A drug is misbranded if:

- a. its labeling is false or misleading in any particular, 21 U.S.C. § 352(a);
- b. its labeling did not bear adequate directions for use, 21 U.S.C. § 352(f)(1);
or
- c. it is a prescription drug and it is dispensed without a valid prescription, 21 U.S.C. § 353(b)(1).

10. Under the FDCA, the term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m).

11. "Peptides" are chemical compounds containing two or more amino acids linked by the carboxyl group of 1 amino acid and the amino group of another.

12. There is an illegitimate market for prescription drugs, the active ingredients in prescription drugs and peptides among bodybuilders and others who engage in weight training, since it is believed that the use of these substances enhance muscle development.

13. When peptides are intended to affect human muscle development, they are "drugs" under the FDCA.

14. The Food and Drug Administration (FDA) monitors websites to ensure that the distribution of drugs and chemicals intended for human consumption is in compliance with the law.

Misbranding of Drugs and Scheme to Defraud

15. From in or about 2010 to in or about January 2014, MARSALA and BUMGARNER sold and distributed misbranded drugs into interstate commerce through Osta-Gain and Spectrum Peptides with the intent to defraud and mislead the FDA by making a series of false and fraudulent representations and omissions of material facts.

16. In order to mislead the FDA and law enforcement officers about the true nature of their business, MARSALA and BUMGARNER falsely and fraudulently posted numerous disclaimers on their websites (www.osta-gain.com, www.spectrumpeptide.com and others) and other materials that the drugs and chemicals sold by MARSALA and BUMGARNER were not for human consumption and use. Specifically, MARSALA and BUMGARNER falsely and fraudulently claimed: "ALL products and services offered are for RESEARCH purposes ONLY. Under NO circumstances shall/should ANY of these materials be used for recreational purposes nor human consumption!"

17. This disclaimer was a ruse to circumvent and defraud the FDA.

18. In reality, MARSALA and BUMGARNER marketed their products (peptides, compounds containing the same active ingredients in prescription drugs and other chemicals) exclusively to individuals for human consumption. Indeed, MARSALA and BUMGARNER's primary market for their drugs was bodybuilders and weight lifters.

19. The chemicals and compounds sold by MARSALA and BUMGARNER were intended for use by bodybuilders to build muscle mass and to counter the side effects of such muscle building drugs. MARSALA's and BUMGARNER's websites offered a very narrow range of chemical compounds and amino acid/peptide products which were used by bodybuilders to increase muscle mass, repair and rebuild muscles, and to treat erectile dysfunction caused by steroid/drug usage. In addition, MARSALA and BUMGARNER sold the necessary "laboratory supplies" (e.g. pipettes) for body builders to administer the products.

20. "Peptides" are chemical compounds containing two or more amino acids linked by the carboxyl group of 1 amino acid and the amino group of another. In general, peptides have not been approved by the FDA and therefore cannot be dispensed for human use.

21. Even though MARSALA and BUMGARNER falsely claimed that their products were for research purposes only, they marketed their company products to humans and individuals with promotions such as Black Friday sales, Christmas sales and free T-Shirts promotions.

22. MARSALA and BUMGARNER spent at least \$50,000 to advertise on and sponsor websites, forums and companies that specifically catered to the bodybuilder and weightlifting communities. Similarly, MARSALA and BUMGARNER attempted to advertise their company and products by sponsoring a weightlifting competition.

23. MARSALA and BUMGARNER directly, and indirectly through other employees, posted messages on these bodybuilder forums to advertise their companies' products to individuals and to generate sales from these forums.

24. MARSALA and BUMGARNER directly, and through others, distributed dosing information to consumers for human consumption.

25. On or about April 16, 2012, MARSALA and BUMGARNER, through their website www.osta-gain.com, sold and thereafter shipped two vials of GnRH (Triptorelin) and two vials of Tamoxifen Citrate (Tamoxifen) to an individual. These drugs were shipped from Charlotte, North Carolina to the undercover agent's P.O. Box in Atlanta, Georgia.

- a. Triptorelin is a prescription drug used by physicians to treat advanced prostate cancer in men and is frequently abused by weightlifters, bodybuilders and other athletes to stimulate the production of testosterone.
- b. Tamoxifen Citrate is the active ingredient in a prescription drug used by physicians to treat breast cancer. Bodybuilders who take steroids, including testosterone, may experience a significant increase in their estrogen level which results in the growth of breast glands and increased fat deposits. The use of Tamoxifen Citrate enables the body to suppress these manifestations.

26. After Osta-Gain was named in an April 2013 national newspaper article about the improper marketing by internet companies and use of "research chemicals" by bodybuilders, MARSALA and BUMGARNER became concerned about increased regulatory scrutiny. For this and other reasons, MARSALA and BUMGARNER abandoned the Osta-Gain website in or about April 2013 and transferred their Osta-Gain business to their newly created Spectrum Peptides company.

27. Spectrum Peptides offered nearly all of the same products as Osta-Gain and advertised in the same manner to individuals for human consumption, primarily bodybuilders.

COUNT ONE

21 U.S.C. §§ 331(a), 333(a)(2), 352(a), 352(f)(1)), 353(b)

28. The United States Attorney re-alleges and incorporates by reference herein all of the allegations contained in paragraphs 1 through 27 of the Bill of Information, and further alleges that:

29. On or about April 16, 2012, in Mecklenburg County, within the Western District of North Carolina, and elsewhere, the defendants,

**JOSEPH MARSALA
and
BRENT BUMGARNER**

aided and abetted by each other and others known and unknown to the United States Attorney, introduced and delivered for introduction into interstate commerce, with the intent to defraud and mislead, drugs, namely two vials (100mcg/2ml) GnRH (Triptorelin) and two vials (30ml-40mg /ml) of Tamoxifen Citrate (Tamoxifen), which were misbranded within the meaning of:

- a. Title 21, U.S.C. § 352(a), in that their labeling was false and misleading in any particular;
- b. Title 21, U.S.C. § 352(f)(1), in that their labeling lacked adequate directions for use; and
- c. Title 21, U.S.C. § 353(b), in that they were prescription drugs dispensed without a valid prescription of a licensed medical practitioner.

All in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

NOTICE OF FORFEITURE

30. Notice is hereby given of 18 U.S.C. § 982, 21 U.S.C. § 334 and 28 U.S.C. § 2461(c). Under Section 2461(c), criminal forfeiture is applicable to any offenses for which forfeiture is authorized by any other statute. The following property is subject to forfeiture in accordance with Section 982, 334, and/or 2461(c):

- a. All property which constitutes or is derived from proceeds of the violations set forth in this bill of information;
- b. All property involved in such violations or traceable to property involved in such violations; and
- c. If, as set forth in 21 U.S.C. § 853(p), any property described in (a) or (b) cannot be located upon the exercise of due diligence, has been transferred or sold to, or deposited with, a third party, has been placed beyond the jurisdiction of the court, has been substantially diminished in value, or has been commingled with other property which cannot be divided without difficulty, all other property of the defendant/s to the extent of the value of the property described in (a) and (b).

31. The following property is subject to forfeiture on one or more of the grounds stated above:

- a. Approximately \$25,982.43 in funds seized during the investigation from First Citizens Bank, Account XX3272, such account held in the name of Osta-Gain, LLC with JOSEPH MARSALA as sole signatory; and
- b. Approximately \$8,030.00 in currency seized during the investigation.

ANNE M. TOMPKINS
UNITED STATES ATTORNEY


KELLI H. FERRY
ASSISTANT UNITED STATES ATTORNEY